

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicant: Wright et al.

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Customer Number: 20,995

Commissioner for Patents
Post Office Box 1450
Alexandria, Virginia 22313-1450

DECLARATION OF KEN WRIGHT UNDER 37 C.F.R. § 1.132

Sir:

I, Ken Wright, declare as follows:

1. I have been involved in Medical Informatics for the last twenty years within large hospital environments in which my primary role was in evaluating medical applications that applied to Radiology. In addition, I have actively participated in a number of societies over the last twenty years relating to Medical Informatics such as HIMMS (Health Information Management Systems), SCAR (Society of Computer Applications in Radiology) and as a practicing Radiologic Technologist (ARRT, CRT). I consider myself skilled in the art of development and implementation of healthcare information management systems that operate in compliance with the Digital Imaging and Communications in Medicine ("DICOM") standard.

2. I am a co-inventor of the invention claimed in U.S. Patent Application 09/761,795, which was filed on 17 January 2001, and which is referred to herein as "the '795 Application".
3. The '795 Application discloses, among other things, systems that can be used to select and automatically record medical image data onto a data storage medium. Such systems typically include an application server that receives medical image data from a medical image database. The medical image data is formatted in a standard medical imaging format used by specialized computers for viewing medical images. The application server allows users to select medical images of interest and search for additional medical images that are related to the selected images. The selected and related medical images can then be recorded onto a portable data storage medium, such as a compact disc, using the standard medical imaging format. A viewing program is also recorded onto the storage medium with the medical images. The viewing program allows the medical images stored on the storage medium to be viewed on widely accessible computers that are not specifically configured with standard medical imaging software.
4. The inventions disclosed in the '795 Application provide a substantial improvement over the conventional methods for accessing and distributing medical image data at the time the invention disclosed in the '795 Application was made. As far as I am aware, before the invention disclosed in the '795 Application was made, existing systems required the use of viewing workstations that were specifically configured to view medical image data stored in a standardized medical imaging format, such as the DICOM format. This substantially limited the distribution and portability of medical image data.
5. I am familiar with the course of prosecution of the '795 Application, including the Office Action mailed on 20 April 2007, in which the Examiner cited U.S. Patent

6,241,668 ("Herzog") in view of U.S. Patent 5,909,551 ("Tahara"), U.S. Patent 5,272,625 ("Nishihara"), U.S. Patent 6,260,021 ("Wong"), and U.S. Patent 6,954,802 ("Sutherland"). I have carefully reviewed these references.

6. Herzog discloses a system for capturing, processing and storing medical image data (1:5–10). The Herzog system includes several devices, referred to as digital imaging modalities, that are configured to acquire medical images; examples of such modalities include a computed tomography unit, a magnetic resonance unit, a digital subtraction unit, and an x-ray unit (2:21–26). The Herzog system also includes a diagnostic station that is configured to acquire medical image data from a number of different sources, such as from the digital imaging modalities (3:23–28), from a digital image archive (3:28–31), or from a scanner used to scan relevant documents (3:32–36). The medical image data acquired by the diagnostic station can be recorded onto a compact disc using a compact disc writer (3:43–49).
7. Other than a statement that certain imaging sources "offer standardized JPEG software interfaces" such that the "images thusly acquired can be made available over the Internet" (4:15–23), Herzog ignores the question of which format should be used to store the medical image data on the compact disc. Furthermore, even assuming that a standardized medical imaging format is to be used, Herzog also ignores the question of how this data could be accessed and viewed on widely accessible computers that are not specifically configured with standard medical imaging software.
8. Sutherland discloses formatting standard medical images such that they can be widely accessed by computer. For example, Sutherland discloses use of PC-based review stations that are "configured with specialized image viewing software that can read specific file formats" (4:9–13). Sutherland further discloses recording a patient study on a medium "that can be viewed by any DICOM-compliant viewing station ... which supports the appropriate modality

objects" (7:13–16). Thus, Sutherland contemplates the need for a DICOM-compliant viewing station, and therefore an ordinarily skilled artisan would not understand Sutherland as suggesting the use of a viewing program that allows for viewing of medical image data on widely accessible computers not specifically configured with standard medical imaging software for viewing of medical images.

9. Tahara discloses an interactive multimedia information recording system (1:8–11). An ordinarily skilled artisan would not look to the teachings of Tahara when seeking to improve upon the shortcomings of conventional systems that require the use of viewing workstations that were specifically configured to view medical image data stored in a standardized medical imaging format, such as the DICOM format. In particular, an ordinarily skilled artisan would not recognize that the multimedia system disclosed in Tahara would be applicable to systems used to manage healthcare information. An ordinarily skilled artisan would not recognize that the Tahara system would be applicable to a system, such as the Sutherland system, that is used to manage medical imaging information in a way that allows medical images stored on a portable recording medium using a standard medical imaging format to be viewed on widely accessible computers that are not specifically configured with standard medical imaging software.
10. Nishihara discloses a medical image data management system for use with a distributed image database and a medical image data filing system (1:6–10). This system allows imaging modalities to extract image filing destination information from a filing destination file and transfer generated images to a filing apparatus that indicated by the extracted filing destination information (10:20–37). An ordinarily skilled artisan would not understand this arrangement to be applicable to the invention disclosed in the '795 Application. Specifically, the system disclosed in Nishihara does not address the shortcomings of medical image data management systems, such as that disclosed in Sutherland, that require the use of viewing workstations that are specifically configured to view

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medical image data stored in a standardized medical imaging format, such as the DICOM format.

11. Wong discloses a computer system used to provide distribution of and access to medical image data (1:7-12). The system optionally includes a security object server that logs an audit trail of user sessions that access the medical image data (10:43-47). An ordinarily skilled artisan would not look to the teachings of Wong when seeking to improve upon the shortcomings of conventional systems, such as the system disclosed in Sutherland, that require the use of viewing workstations that are specifically configured to view medical image data stored in a standardized medical imaging format, such as the DICOM format. In particular, an ordinarily skilled artisan would not recognize that the audit system disclosed in Wong would help address the shortcomings of the Sutherland system, especially since the shortcomings of the Sutherland system are not related to the features disclosed in Wong.

12. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued therefrom.

Dated: 7-19-07

By:



Ken Wright

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